



Barco NV
% Ms. Julie Vandecandelaere
Regulatory Affairs Officer
President Kennedypark 35
Kortrijk, W-VL 8500
BELGIUM

March 21, 2023

Re: K230520

Trade/Device Name: Nio Color 2MP (MDNC-2521); Nio Color 3MP (MDNC-3521)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: PGY
Dated: February 27, 2023
Received: February 27, 2023

Dear Ms. Vandecandelaere:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. Behind the signature, there is a large, light blue watermark of the letters "FDA".

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices
and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K230520

Device Name

Nio Color 2MP (MDNC-2521)
Nio Color 3MP (MDNC-3521)

Indications for Use (Describe)

The display is intended to be used for displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.

The display is intended to be used for displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.
The display may be used in dental applications.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary (in accordance with 21 CFR 807.92)

K230520

1. Company	Barco N.V. Healthcare Division 35 President Kennedypark B-8500 Kortrijk BELGIUM
2. Contact person	Julie Vandecandelaere Regulatory Affairs Officer Tel: +32 (0)56 26 13 19 julie.vandecandelaere@barco.com
3. Date of submission	27 February 2023
4. Device information	Trade name/model: Nio Color 2MP (MDNC-2521) Nio Color 3MP (MDNC-3521) Common name: MDNC-2521 MDNC-3521 Classification name: System, image processing, Radiological Classification code: PGY Device classification: Class 2 Regulation number: 892.2050 Regulation name: Medical Image Management and Processing System
5. Predicate device	MDNC-2521: Nio Color 2MP (MDNC-2221) cleared under 510(K) K133663 Common name: MDNC-2221 Classification name: System, image processing, Radiological Classification code: LLZ Device classification: Class 2 Regulation number: 892.2050 Regulation name: Medical Image Management and Processing System MDNC-3521: Nio Color 3MP (MDNC-3421) cleared under 510(k) K170837 Common name: MDNC-3421 Classification name: System, image processing, Radiological Classification code: PGY

	<p>Device classification: Class 2</p> <p>Regulation number: 892.2050</p> <p>Regulation name: Medical Image Management and Processing System</p>
<p>6. Device description</p>	<p>Both the Nio Color 2MP (MDNC-2521) and the Nio Color 3MP (MDNC-3521) are medical computer displays designed for general radiology imaging applications. The MDNC-3521 model can also be used in dental applications. The devices can also be used for home reading in radiology.</p> <p>The MDNC-2521 is a derivative of the MDNC-2221. The MDNC-3521 is a derivative of the MDNC-3421.</p> <p>The modified displays are effectively identical to the respective predicate devices except for the following changes:</p> <ul style="list-style-type: none"> ✓ Updated LCD panel with same resolution and dimensions compared to the respective predicate devices ✓ New housing, display stand and internal mechanics, with similar functionality and design principle compared to the respective predicate devices ✓ Updated internal electronics boards, with similar functionality and design principle compared to the respective predicate devices ✓ Updated firmware, with similar functionality and design principle compared to the respective predicate devices ✓ New packaging, with similar functionality and design principle compared to the respective predicate devices or any other Barco diagnostic display ✓ Rephrasing of the intended usage environment, because of the evolution towards more home reading in radiology ✓ Small update in the intended user description <p>The modified device has the following similarities compared to the unmodified device:</p> <ul style="list-style-type: none"> ✓ The same intended use ✓ The same operating principle ✓ The same fundamental technology <p>The displays can be used optionally with QAWeb Enterprise software, listed under D332294 as a class 1 device with product code LHO. QAWeb Enterprise is a calibration software that is intended as a quality assurance software for the displays. QAWeb Enterprise software helps to keep the display DICOM compliant.</p> <p>The display can be used optionally with Intuitive Workflow Tools, cleared in K191845 as a class 2 device with product code PGY. The Intuitive Workflow Tools are accessories for image enhancement on diagnostic displays:</p> <ul style="list-style-type: none"> • SpotView: The Barco SpotView display feature allows focusing on a region of interest in an image by boosting the display's backlight such that the maximum luminance is provided inside the region of interest. SpotView also enables focused observation during reading by dimming images outside the region of interest and increasing the contrast in this region. Also magnification and inversion of pixels are possible with SpotView. • AAM – Application Appearance Manager: This workflow tool allows you to set the luminance as well as the color space for each application that is on the workstation. There are often multiple windows open on a screen, but not all of them need the high brightness of the diagnostic applications.

	<p>These applications are addressed by the general term 'Intuitive Workflow Tools'.</p> <p>The integration of the Intuitive Workflow Tools with the displays have been de-risked, verified and validated to ensure that they do not affect the safety and effectiveness of the displays.</p> <p>The display can be marketed with or without the Barco MXRT display controller boards. The display controller board is installed in a PACS workstation computer, connected to the display.</p>																																																			
7. Intended Use of the Device	<p>MDNC-2521: The display is intended to be used for displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.</p> <p>MDNC-3521: The display is intended to be used for displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners. The display may be used in dental applications.</p> <p>Note: There are no changes to the indications for use statement from that of the unmodified device.</p>																																																			
8. Comparison of technological characteristics	<table border="1"> <thead> <tr> <th data-bbox="440 863 740 919">Item</th> <th data-bbox="740 863 1117 919">Predicate Device (K133663)</th> <th data-bbox="1117 863 1485 919">Device for which listing is sought</th> </tr> </thead> <tbody> <tr> <td data-bbox="440 919 740 951">Device name</td> <td data-bbox="740 919 1117 951">Nio Color 2MP (MDNC-2221)</td> <td data-bbox="1117 919 1485 951">Nio Color 2MP (MDNC-2521)</td> </tr> <tr> <td data-bbox="440 951 740 1014">Screen technology</td> <td data-bbox="740 951 1117 1014">IPS-Pro</td> <td data-bbox="1117 951 1485 1014">IPS-SFT Color LCD</td> </tr> <tr> <td data-bbox="440 1014 740 1077">Active screen size (diagonal)</td> <td data-bbox="740 1014 1117 1077">540 mm (21.3")</td> <td data-bbox="1117 1014 1485 1077">541 mm (21.3")</td> </tr> <tr> <td data-bbox="440 1077 740 1140">Active screen size (HxV)</td> <td data-bbox="740 1077 1117 1140">432 x 324 mm (17.0 x 12.8")</td> <td data-bbox="1117 1077 1485 1140">433 x 325 mm (17.1 x 12.8")</td> </tr> <tr> <td data-bbox="440 1140 740 1192">Aspect ratio (H:V)</td> <td data-bbox="740 1140 1117 1192">4:3</td> <td data-bbox="1117 1140 1485 1192">4:3</td> </tr> <tr> <td data-bbox="440 1192 740 1287">Resolution</td> <td data-bbox="740 1192 1117 1287">2MP (1600 x 1200 pixels)</td> <td data-bbox="1117 1192 1485 1287">2MP (1600 x 1200 pixels)</td> </tr> <tr> <td data-bbox="440 1287 740 1318">Color imaging</td> <td data-bbox="740 1287 1117 1318">Yes</td> <td data-bbox="1117 1287 1485 1318">Yes</td> </tr> <tr> <td data-bbox="440 1318 740 1350">Gray imaging</td> <td data-bbox="740 1318 1117 1350">Yes</td> <td data-bbox="1117 1318 1485 1350">Yes</td> </tr> <tr> <td data-bbox="440 1350 740 1381">Bit depth</td> <td data-bbox="740 1350 1117 1381">30 bit</td> <td data-bbox="1117 1350 1485 1381">30 bit</td> </tr> <tr> <td data-bbox="440 1381 740 1413">Viewing angle (H, V)</td> <td data-bbox="740 1381 1117 1413">178°</td> <td data-bbox="1117 1381 1485 1413">178°</td> </tr> <tr> <td data-bbox="440 1413 740 1497">Uniformity Correction</td> <td data-bbox="740 1413 1117 1497">ULT</td> <td data-bbox="1117 1413 1485 1497">ULT</td> </tr> <tr> <td data-bbox="440 1497 740 1644">SteadyColor Calibration</td> <td data-bbox="740 1497 1117 1644">No</td> <td data-bbox="1117 1497 1485 1644">Yes (in MXRT Display Controller), when used as a system with MXRT Display Controller & QAWeb Enterprise</td> </tr> <tr> <td data-bbox="440 1644 740 1707">Ambient Light Compensation (ALC)</td> <td data-bbox="740 1644 1117 1707">Yes, reading room selection</td> <td data-bbox="1117 1644 1485 1707">Yes, reading room selection</td> </tr> <tr> <td data-bbox="440 1707 740 1738">Ambient Light Sensor</td> <td data-bbox="740 1707 1117 1738">Yes</td> <td data-bbox="1117 1707 1485 1738">Yes</td> </tr> <tr> <td data-bbox="440 1738 740 1770">Front sensor</td> <td data-bbox="740 1738 1117 1770">Yes</td> <td data-bbox="1117 1738 1485 1770">Yes</td> </tr> <tr> <td data-bbox="440 1770 740 1810">Maximum luminance (panel typical)</td> <td data-bbox="740 1770 1117 1810">800 cd/m²</td> <td data-bbox="1117 1770 1485 1810">1000 cd/m²</td> </tr> </tbody> </table>	Item	Predicate Device (K133663)	Device for which listing is sought	Device name	Nio Color 2MP (MDNC-2221)	Nio Color 2MP (MDNC-2521)	Screen technology	IPS-Pro	IPS-SFT Color LCD	Active screen size (diagonal)	540 mm (21.3")	541 mm (21.3")	Active screen size (HxV)	432 x 324 mm (17.0 x 12.8")	433 x 325 mm (17.1 x 12.8")	Aspect ratio (H:V)	4:3	4:3	Resolution	2MP (1600 x 1200 pixels)	2MP (1600 x 1200 pixels)	Color imaging	Yes	Yes	Gray imaging	Yes	Yes	Bit depth	30 bit	30 bit	Viewing angle (H, V)	178°	178°	Uniformity Correction	ULT	ULT	SteadyColor Calibration	No	Yes (in MXRT Display Controller), when used as a system with MXRT Display Controller & QAWeb Enterprise	Ambient Light Compensation (ALC)	Yes, reading room selection	Yes, reading room selection	Ambient Light Sensor	Yes	Yes	Front sensor	Yes	Yes	Maximum luminance (panel typical)	800 cd/m ²	1000 cd/m ²
Item	Predicate Device (K133663)	Device for which listing is sought																																																		
Device name	Nio Color 2MP (MDNC-2221)	Nio Color 2MP (MDNC-2521)																																																		
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Ambient Light Sensor	Yes	Yes																																																		
Front sensor	Yes	Yes																																																		
Maximum luminance (panel typical)	800 cd/m ²	1000 cd/m ²																																																		

DICOM calibrated luminance	500 cd/m ²	600 Cd/m ²
Contrast ratio (panel typical)	1400:1	2000:1
Response time ((Tr + Tf)/2) (typical)	10 ms	12 ms ^[*] (gray-to-gray average)
Housing color	RAL 9003 / RAL 9004	Black (RAL 9004) / White (RAL 9003)
Video input signals	1x DVI 1x DisplayPort	2x DisplayPort 1.4
USB ports	1x USB 2.0 upstream (endpoint) 2x USB 2.0 downstream	2x USB-B 2.0 upstream (endpoint) 5x USB-A 2.0 downstream (of which 1 charge port)
Power rating	24 VDC, 3.75 A	24 VDC, 4 A
Power consumption	50 W (nominal) < 1 W (hibernate)	37 W (nominal) < 0.35 W (hibernate)
Dimensions with stand (W x H x D)	Portrait: 378 x 525~625 x 235 mm Landscape: 491 x 466~566 x 235 mm	Portrait: 351 x 531~631 x 225 mm Landscape: 491 x 462~562 x 225 mm
Dimensions without stand (W x H x D)	Portrait: 378 x 491 x 83 mm Landscape: 491 x 378 x 83 mm	Portrait: 351 x 491 x 64 mm Landscape: 491 x 351 x 64 mm
Dimensions packaged (W x H x D)	655 x 388 x 495 mm	455 x 210 x 770 mm
Net weight with stand	With protective cover: 12.6 kg Without protective cover: 11.3 kg	With protective cover: 8.8 kg Without protective cover: 7.7 kg
Net weight without stand	With protective cover: 7.6 kg Without protective cover: 6.3 kg	With protective cover: 5.8 kg Without protective cover: 4.7 kg
Net weight packaged	With protective cover: 16.8 kg (without optional accessories) Without protective cover: 15.5 kg (without optional accessories)	With protective cover: 12.2 kg (without optional accessories) Without protective cover: 11.2 kg (without optional accessories)
Tilt	-5° to +25°	-10° to +30°
Swivel	-30° to +30°	-30° to +30°
Pivot	90°	90°
Height adjustment range	100 mm	100 mm
Mounting standard	VESA (100 mm)	VESA (100 mm)
Screen protection	Protective, anti-reflective glass cover (optional)	Protective, anti-reflective front glass (optional)
Recommended modalities	All digital images, except digital mammography	All digital images, except digital mammography

Supplied accessories	User guide Documentation disc System sheet Video cable Mains cable(s) USB cable External power supply	User guide Documentation disc System sheet Video cables USB cables Mains cables External power supply
Optional accessories	Graphics board	Display controller
QA software	QAWeb	QAWeb
Warranty	5 years, including 20000 hrs backlight warranty	5 years, including 20000 hrs backlight warranty
Operating temperature	0 °C to 35 °C (15 °C to 30 °C within specs)	0 °C to 35 °C (20 °C to 30 °C within specs)
Storage temperature	-20 °C to 60 °C	-20 °C to 60 °C
Operating humidity	8 % to 80 % (non- condensing)	8% to 80% (non- condensing)
Storage humidity	5% to 85% (non- condensing)	5% to 85% (non- condensing)
Minimum operating pressure	70 kPa minimum	70 kPa minimum
Storage pressure	50 to 106 kPa	50 to 106 kPa

Item	Predicate Device (K170837)	Device for which listing is sought
Device name	Nio Color 3MP (MDNC-3421)	Nio Color 3MP (MDNC-3521)
Screen technology	IPS-TFT Color LCD	IPS-SFT Color LCD
Active screen size (diagonal)	540 mm (21.3")	541 mm (21.3")
Active screen size (HxV)	432 x 324 mm (17.0 x 12.8")	433 x 325 mm (17.1 x 12.8")
Aspect ratio (H:V)	4:3	4:3
Resolution	3MP (2048 x 1536 pixels)	3MP (2048 x 1536 pixels)
Color imaging	Yes	Yes
Gray imaging	Yes	Yes
Bit depth	30 bit	30 bit
Viewing angle (H, V)	178°	178°
Uniformity Correction	ULT	ULT
SteadyColor Calibration	No	Yes (in MXRT Display Controller), when used as a system with MXRT Display Controller & QAWeb Enterprise
Ambient Light Compensation (ALC)	Yes, reading room selection	Yes, reading room selection
Ambient Light Sensor	Yes	Yes
Front sensor	Yes	Yes
Maximum luminance (panel typical)	900 cd/m ²	1050 cd/m ²

DICOM calibrated luminance	500 cd/m ²	600 Cd/m ²
Contrast ratio (panel typical)	1400:1	2000:1
Response time ((Tr + Tf)/2) (typical)	20 ms	12 ms ^[*] (grey-to-grey average)
Housing color	RAL 9003 / RAL 9004	Black (RAL 9004) / White (RAL 9003)
Video input signals	DVI-D Dual Link DisplayPort	2x DisplayPort 1.4
USB ports	1x USB 2.0 upstream (endpoint) 3x USB 2.0 downstream	2x USB-B 2.0 upstream (endpoint) 5x USB-A 2.0 downstream (of which 1 charge port)
Power rating	24 VDC, 4 A	24 VDC, 4 A
Power consumption	50 W (nominal)	45 W (nominal) < 0.35 W (hibernate)
Dimensions with stand (W x H x D)	Portrait: 378 x 528~628 x 235 mm Landscape: 491 x 472~572 x 235 mm	Portrait: 351 x 531~631 x 225 mm Landscape: 491 x 462~562 x 225 mm
Dimensions without stand (W x H x D)	Portrait: 378 x 491 x 84 mm Landscape: 491 x 378 x 84 mm	Portrait: 351 x 491 x 64 mm Landscape: 491 x 351 x 64 mm
Dimensions packaged (W x H x D)	500 x 280 x 670 mm	455 x 210 x 770 mm
Net weight with stand	With protective cover: 11.2 kg Without protective cover: 10.7 kg	With protective cover: 8.8 kg Without protective cover: 7.7 kg
Net weight without stand	With protective cover: 6.2 kg Without protective cover: 5.7 kg	With protective cover: 5.8 kg Without protective cover: 4.7 kg
Net weight packaged	With protective cover: 15.7 kg (without optional accessories) Without protective cover: 15.2 kg (without optional accessories)	With protective cover: 12.2 kg (without optional accessories) Without protective cover: 11.2 kg (without optional accessories)
Tilt	-10° to +30°	-10° to +30°
Swivel	-45° to +45°	-30° to +30°
Pivot	90°	90°
Height adjustment range	100 mm	100 mm
Mounting standard	VESA (100 mm)	VESA (100 mm)
Screen protection	Protective, anti-reflective glass cover (optional)	Protective, anti-reflective front glass (optional)
Recommended modalities	All digital images, except digital mammography	All digital images, except digital mammography

	Supplied accessories	User guide Documentation disc System sheet Video cable Mains cable(s) USB cable External power supply	User guide Documentation disc System sheet Video cables USB cables Mains cables External power supply
	Optional accessories	Graphics board	Display controller
	QA software	QAWeb	QAWeb
	Warranty	5 years, including 20000 hrs backlight warranty	5 years, including 20000 hrs backlight warranty
	Operating temperature	0 °C to 40 °C (15 °C to 35 °C within specs)	0 °C to 35 °C (20 °C to 30 °C within specs)
	Storage temperature	-20 °C to 60 °C	-20 °C to 60 °C
	Operating humidity	8 % to 80 % (non- condensing)	8% to 80% (non- condensing)
	Storage humidity	5% to 85% (non- condensing)	5% to 85% (non- condensing)
	Minimum operating pressure	70 kPa minimum	70 kPa minimum
	Storage pressure	50 to 106 kPa	50 to 106 kPa
	<p>[*] The intrinsic response time of the new LCD panel on the modified device is further improved with Barco's RapidFrame technology, a proprietary medical overdrive algorithm which improves the temporal response of the system.</p> <p>The technological characteristics shown above show that the devices MDNC-2521 and MDNC-3521 are substantially equivalent to their respective predicate devices MDNC-2221 and MDNC-3421 and they do not reveal new issues of safety and performance.</p>		
9. Performance testing	<p>The below performance bench tests are performed and corresponding results reported for the modified devices MDNC-2521 and MDNC-3521 in comparison to the already cleared device MDNC-3421 as per the <i>Physical Laboratory Testing</i> instructions in "Guidance for Industry and FDA Staff: Display Devices for Diagnostic Radiology", issued in 2022:</p> <ul style="list-style-type: none"> • Spatial resolution – MTF • Pixel defects, Artifacts • Temporal Response • Maximum and Minimum Luminance • Luminance response, Conformance to DICOM GSDF • Angular Dependency of Luminance • Luminance uniformity • Reflection coefficient – Display Reflectance incl. Specular, Diffuse & Haze coefficients • Veiling glare or small-spot contrast • Color tracking <p>The tests showed that the modified devices MDNC-2521 and MDNC-3521 have similar characteristics compared to already cleared device MDNC-3421 and did not reveal new issues of safety and performance.</p> <p>Additionally, the modified devices MDNC-2521 and MDNC-3521 are compliant to EMC and Safety standards.</p> <p>No animal testing or clinical testing has been performed.</p>		

10. Conclusion	<p>The Nio Color 2MP (MDNC-2521) and Nio Color 3MP (MDNC-3521) were found to be substantially equivalent to their respective predicate devices MDNC-2221 and MDNC-3421, due to the following reasons:</p> <ul style="list-style-type: none">a) Device and predicate device have the same intended use respectivelyb) The technological characteristics differences from the predicate device do not affect safety or effectivenessc) Bench testing showed that the device has similar characteristics compared to the already cleared device and did not reveal new issues of safety and performance.
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